

EXHIBIT 12

Art Unit 125

Paper No. 19

Appeal No. 87-2039

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SEP 15 1989

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HEARD:  
August 8, 1989

BOARD OF PATENT APPEALS  
& INTERFERENCES

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte Charles E. Clum  
and  
David M. Isaacson

- - -

Application for Patent filed February 11, 1985, Serial  
No. 700,165, a Continuation-in-Part of Serial No. 571,763 filed  
January 18, 1984. Skin Care Compositions.

Steven P. Berman et al. for appellants.

Primary Examiner - Leonard Schenkman.  
Examiner - J. Lipovsky.

Before Pellman, Winters and J. Smith, Examiners-in-Chief.  
Pellman, Examiner-in-Chief.

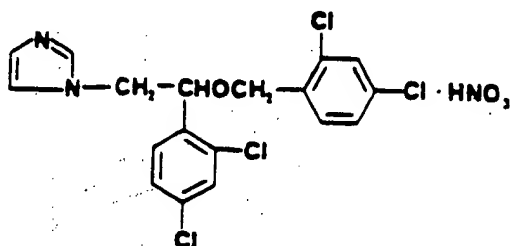
This is an appeal from the examiner's decision finally  
rejecting claims 1, 4, 5 and 6, all of the claims remaining in  
the application.

The subject matter on appeal involves a composition  
comprising one part of miconazole nitrate and 60 to 333 parts of

zinc oxide. The invention also concerns a method for treating diaper rash by applying the noted composition to the affected skin area (claims 5 and 6). To describe the invention in greater detail, claims 1 and 4 are reproduced as follows:

1. A skin care composition comprising as the active components

(a) miconazole nitrate of the formula



(b) zinc oxide;

wherein the miconazole nitrate and zinc oxide are present in a ratio of from about 1:60 to about 1:333.

4. The composition of claim 1 wherein the miconazole nitrate and zinc oxide are present in a ratio of about 1:60.

For evidence of obviousness, the reference identified below is cited by the examiner:

Schmidt-Ruppin et al. (Schmidt-Ruppin) 4,318,926 Mar. 9, 1982

All of the claims stand rejected for being unpatentable (35 U.S.C. 103) in view of Schmidt-Ruppin. The examiner notes that the patentee discloses topical creams and ointments containing zinc oxide (column 8, lines 30-34), as well as other active substances, such as miconazole (column 9, lines 9-15). It is the examiner's position that the determination of the optimal proportions and target use would have been obvious alternatives to that disclosed by the reference.

At page 6 of the principal brief, appellants contend that the reference discloses compositions containing an anthracene-type compound to act upon the central nervous system of the person to be treated. We are told that to obtain the claimed

composition, one would have to formulate the composition containing the anthracene compound and then delete said compound and adjust the ratios of the remaining components. Appellants stress that the two components of the claimed composition are present in specific ratios which exhibit synergistic interaction.

Accordingly, appellants urge that the examiner has drawn incorrect conclusions not justifiable in view of the teachings of the cited art.

After carefully considering the arguments and supporting evidence of appellants and of the examiner, we agree with the examiner that the reference would have established a prima facie case of obviousness, but agree with appellants that the data in the specification and in the declarations adequately rebut the inference of obviousness established by the cited reference.

The Schmidt-Ruppin patent clearly teaches a cream or ointment containing zinc oxide and miconazole. Additionally, it would have been obvious to employ a significantly larger concentration of the zinc oxide than the miconazole merely from an economical standpoint. That is, the selection of zinc oxide as the vehicle for topically administering a small quantity of miconazole would have been dictated by the relatively low price of the zinc oxide. Although the reference composition would necessarily include a compound such as 9-[(methylamino)methyl]-9,10-dihydro-9, 10-ethanoanthracene, the presence of such a substance is not excluded by the language of appellants' claims which recite "comprising". Compare the holding in In re Fenton, 59 CCPA 708, 451 F.2d 640, 171 USPQ 693 (1971). Also compare the rationale in In re Janakirama-Rao, 50 CCPA 1312, 317 F.2d 951, 137 USPQ 893 (1963).

Having determined that a prima facie case of obviousness has been established, we now consider anew all of the evidence of record, in line with the holding in In re Johnson, 747 F.2d 1456,

223 USPQ 1260 (Fed. Cir. 1984). In this connection, appellants provide data as to the asserted synergistic activity of their composition at Tables I through IV, at pages 12 through 15 of the specification, and in four declarations.

The examiner, at page 3 of the answer, seems to find that the results in the specification substantiate synergism for the proportions of 1:84 to 1:239. However, the examiner holds that the data for a proportion of one part of miconazole nitrate to 42 parts of zinc oxide establishes a difference in inhibition that is "not seen to be of a degree which definitely reflects synergism." The examiner evaluates a declaration by Dr. David M. Isaacson signed March 10, 1986 as being "persuasive in substantiating synergism of a 1:60 mixture of miconazole nitrate and zinc oxide against one organism; Straphylcoccus [sic] aureus."

Regarding a declaration by Dr. Bruce Semple, signed March 7, 1986, the examiner responds with the statement that declarant omitted the data upon which his conclusions are based and with respect to a second declaration by Dr. Semple, signed August (no day) 1986, the examiner explains that the demonstrated enhancement of microbial inhibition for Candida albicans is "considered minimal and not seen to be of a degree which definitively reflects synergism, particularly when viewed in conjunction with the data of Table III (page 14 of spec.) where appellant [sic, appellants] can substantiate synergism for a compositional ratio no lower than 1:240." The examiner sets forth his position notwithstanding the assurance in Dr. Semple's second declaration that the results exhibit a statistically significant synergistic effect. No mention is made of the declaration by Dr. James J. Leyden, signed March 17, 1986, offering a substantiating opinion.

We cannot subscribe to the examiner's conclusions in the face of appellants' evidence. To the extent that the examiner

Appeal No. 87-2039

appears to agree that Dr. Isaacson's declaration shows synergism at a 1:60 ratio for S. aureus, this would be sufficient to establish the patentability of appellants' claims. Compare In re Chupp, 816 F.2d 643, 2 USPQ 2d 1437 (Fed. Cir. 1987), which is directly on point.

Furthermore, insofar as the examiner disagrees with the declarants as to the significance of the data, it is insufficient for him merely to substitute his opinion for that of recognized experts in the art. See In re Zeidler, 682 F.2d 961, 215 USPQ 490 (CCPA 1982). In the absence of logical scientific reasoning or factual data, showing error in the evidence of non-obviousness, the objective truth of the findings by recognized experts in the art must be accepted. The examiner's bare opinion, that an enhancement of microbial inhibition of 8 to 25% is minimal, can be given little probative weight by us in balancing the evidence of obviousness against that of non-obviousness. See In re Saunders, 58 CCPA 1316, 1324, 444 F.2d 599, 170 USPQ 213 (1971).

Consequently, for the reasons expressed above, the examiner's decision rejecting claims 1, 4, 5 and 6 is reversed.

REVERSED

Irving R. Pellman  
Irving R. Pellman  
Examiner-in-Chief

*SD Winters*  
Sherman D. Winters  
Examiner-in-Chief

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